# REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 3-I-07

Subject: Amendment to Opinion E-9.095, "Trademarks, Patents, Copyrights, and Other Legal Restrictions on Medical Procedures"

Presented by: Mark A. Levine, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws (Jane C.K. Fitch, MD, Chair)

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## INTRODUCTION

At the 2006 Annual Meeting of the AMA House of Delegates adopted Resolution 1, "Trademarks, Patents, Copyrights, and Other Legal Restrictions on Medical Procedures," as introduced by the Missouri Delegation. This resolution requested the Council on Ethical and Judicial Affairs (CEJA) to study and evaluate whether there is an ethical difference between the use of patents for medical procedures and the use of various other legal devices to limit access to new medical procedures, a term that includes medical techniques and technical maneuvers. The resolution also asked CEJA to study and evaluate whether to affirm Opinion E-9.095, "Patenting of Medical Procedures," or to amend it to prohibit the use of other means, in addition to patents, to limit access to medical procedures.

## BACKGROUND

Resolution 1 is broad in scope and requests CEJA to study a number of intellectual property regimes that can affect the use of new medical procedures. The report focuses primarily on trade secrecy and confidentiality agreements because of the limited application that copyright or trademark law could have on medical procedures, including medical techniques.

Copyright law generally protects the expression of an idea, rather than the underlying idea itself. In the context of medical procedures, a copyright allows for the protection of a document or video or audio aid that explains a procedure, but it does not pertain to the procedure itself. Copyright law specifically exempts from protection any "idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work."[1] For example, a physician may teach students a procedure using the information contained in a textbook, but cannot photocopy extensive portions of the textbook for sale to students without permission from the copyright holder.

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* Reports of the Council on Ethical and Judicial Affairs are assigned to the reference committee on Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

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Likewise, trademark law provides no protection for the underlying medical procedure, only its distinct name. Generally, trademark law provides protection to words or symbols to identify the source of goods or services. A physician may call an invented or improved procedure by his or her own name, such as "The Smith Procedure," but protection extends only to rights associated with use of that name. In general, the procedure cannot be given a different name by a third party, nor can this name be assigned to another procedure, but there are no restrictions on using a procedure that is trademarked.

Neither copyright nor trademark presents an absolute obstacle to dissemination of information concerning medical procedures, although they may limit such dissemination. It is likely for this reason that the *Code of Medical Ethics* has always focused on patents rather than these other forms of intellectual property.

Until the middle of the 20th Century, the *Code of Medical Ethics* contained a prohibition on the patenting of medical devices. The original 1847 edition of *The Code of Ethics of the American Medical Association* provided that "[e]qually derogatory to professional character is it, for a physician to hold a patent for any surgical instrument, or medicine…." Similarly, in 1903, 1912, and 1947, the AMA reaffirmed the prohibition against patents on surgical instruments, appliances, and medicines.

Subsequently, the AMA began to recognize the benefits of allowing physician-inventors to retain rights in inventions and the policy was revised to allow patents for devices by the mid-1950s, and later to allow for certain patents related to human genes. Notably, the Opinion permitting patents on devices did not mention procedure patents. In fact, Opinion E-9.08, "New Medical Procedures," added in the mid-1980s, provided that physicians should share knowledge, an indication that the medical profession remained somewhat ambivalent regarding the restrictions entailed by patents.

At the 1995 Annual Meeting of the House of Delegates, amid growing concern for the effect that procedure patents would have—especially in light of increasing numbers of these patents and lawsuits seeking enforcement—CEJA submitted a report entitled "Patenting of Medical Procedures." This report carefully laid out the basis for prohibiting the patenting of medical procedures and concluded that the best interest of patients and the profession militated against allowing such patents. The corresponding Opinion E-9.095, "Patenting of Medical Procedures," prohibits procedure and technique patents because such patents pose "substantial risks to the effective practice of medicine by limiting the availability of new procedures to patients and should be condemned on this basis."[2] Principle V of the AMA's *Principle of Medical Ethics*, which lays out physicians' ethical responsibility to contribute to and share scientific knowledge, is the foundation of this Opinion. Preventing the dissemination of knowledge for financial gain or fame can have a negative impact on patients and would contravene Principle VIII.

U.S. patent law allows for the patenting of medical procedures. Essentially, "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" may be patented.[3] However, in 1996, Congress passed legislation[4] that protects medical practitioners and related entities from claims of infringement in specified circumstances. This

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provides limited protection for physicians and hospitals in the clinical use of patented medical procedures.

TRADE SECRETS AND MEDICAL PROCEDURES

Protection for the discovery of a new medical procedure or improvement of an existing procedure is not limited to patents. Trade secret law, including contractual arrangements to prevent the dissemination of knowledge under what is known as a confidentiality agreement, can also be employed to limit the dissemination of new medical knowledge.

Trade secret law is based primarily on state law rather than a comprehensive federal act. It can be used to protect the same information as patent law—such as a device, procedure, or method of use—but it does not require the public disclosures that patents do. Essentially, if the person maintaining the trade secret can keep it out of the realm of public knowledge, he or she in effect can prevent another from using the subject of the trade secret. If the trade secret is made known through improper means, such as corporate espionage or a departing employee violating a confidentiality agreement, the person holding the trade secret may pursue damages for violation of this right and still be able to prevent the use of any information gained through the improper disclosure.

The responsibility to prevent disclosure rests with the holder of the trade secret. If the holder inadvertently releases information that others can rightfully discover, the trade secret will no longer exist. Additionally, if another person discovers the same device or procedure through legitimate means and makes that information publicly available, the trade secret will cease to exist. The primary difference between a patent and a trade secret is that the public disclosure of a trade secret destroys legal protection, while the publicly available disclosure of the subject matter of a patent is required. Additionally, a patent lasts for a definite time while a trade secret lasts as long as there is a protected secret.

The *Code of Medical Ethics* contains policy that speaks to inhibiting the spread and use of medical knowledge. Opinion E-9.08, “New Medical Procedures,” presents a strong rationale for disallowing the use of trade secrets to protect medical procedures. It states that “[p]hysicians have an obligation to share their knowledge and skills and to report the results of clinical and laboratory research.”[5] Moreover, “[t]he intentional withholding of new medical knowledge, skills, and techniques from colleagues for reasons of personal gain is detrimental to the medical profession and society and is to be condemned.” Accordingly, it could be said that trade secrets fall under this Opinion, since their purpose is “intentional withholding” for “personal gain.” However, Opinion E-9.08 does not explicitly address this legal means.

Likewise, Opinion E-9.095, “Patenting of Medical Procedures,” discusses the hindrance of dissemination of medical procedures, but is narrow in scope and does not address any legal theory other than patents. It provides that “[t]he patenting of medical procedures poses substantial risks to the effective practice of medicine by limiting the availability of new procedures to patients and should be condemned on this basis.”

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The justification for designating medical procedure patents as unethical is that dissemination of new medical knowledge will be inhibited, thus harming patients who might have benefited from the patented procedure. This reasoning is even stronger for trade secrets: the end result of maintaining a trade secret is limited dissemination or none at all. Like patents, the holder of a trade secret can choose permissible uses of a procedure; unlike patents, the public can be prevented from obtaining the knowledge for future innovations. This limitation on medical knowledge presents additional dangers to patients by preventing others from reviewing or testing the procedure for safety and efficacy.

## CONCLUSION

Opinion E-9.095 was intended to protect the integrity of the medical profession by ensuring access to medical procedures that might benefit patients. The current Opinion applies to seeking, securing, or enforcing patents, and does not address other methods to limit dissemination of medical knowledge. The use of trade secrets, including confidentiality agreements, to prevent this dissemination is just as detrimental, if not more so, than medical procedure patents. Although it is unknown how pervasive the use of trade secrecy is in medicine, the end result of its use is to prevent widespread adoption of medical procedures and techniques for personal gain, potentially at the expense of patients' safety and access to quality care. The Council concludes that Opinion E-9.095 should be amended to cite the use of trade secrets and confidentiality agreements, along with patents, on medical procedures as unethical and to further emphasize the policy's emphasis on sharing medical knowledge.

## RECOMMENDATION

The Council recommends that Opinion E-9.095, "Patenting of Medical Procedures," be amended as follows and the remainder of the Report be filed.

> E-9.095 The Use of Patents and Other Means to Limit Availability of ~~Patenting of~~ Medical Procedures
>
> Physicians have~~A physician has the~~ ethical responsibilities~~responsibility~~ not only to learn from but also, when possible, to contribute to the total store of scientific knowledge ~~when possible~~. Physicians should strive to advance medical science and make their achievements~~advances~~ known through publication or other means of disseminating such information. This encourages physicians to innovate and to share ensuing advances.~~to patients, colleagues, and the public. This obligation provides not merely incentive but imperative to innovate and share the ensuing advances.~~
>
> The use of patents, trade secrets, confidentiality agreements, or other means to limit the availability~~patenting~~ of medical procedures places significant limitation on the dissemination of medical knowledge, and is therefore unethical.~~poses substantial risks to the effective practice of medicine by limiting the availability of new procedures to patients and should be condemned on this basis. Accordingly, it is unethical for physicians to seek, secure, or enforce patents on medical procedures.~~ (V, VII)

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1 Issued June 1996 based on the report "Ethical Issues in the Patenting of Medical Procedures,"
2 adopted June 1995 (Food & Drug Law J. 1998; 53: 341-57).
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4 (Modify HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than $500 to implement.

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APPENDIX- PROPOSED OPINION AMENDMENTS (CLEAN)

E-9.095 The Use of Patents and Other Means to Limit Availability of Medical Procedures

Physicians have ethical responsibilities not only to learn from but also, when possible, to contribute to the total store of scientific knowledge. Physicians should strive to advance medical science and make their achievements known through publication or other means of disseminating such information. This encourages physicians to innovate and to share ensuing advances.

The use of patents, trade secrets, confidentiality agreements, or other means to limit the availability of medical procedures places significant limitation on the dissemination of medical knowledge, and is therefore unethical. (V, VII)

Issued June 1996 based on the report "Ethical Issues in the Patenting of Medical Procedures," adopted June 1995 (Food & Drug Law J. 1998; 53: 341-57).

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**REFERENCES**

[1] United States Copyright Act, 17 U.S.C.S. § 102(b) (Matthew Bender 2006).
[2] American Medical Association. Opinion 9.095 Patenting of Medical Procedures. *AMA Code of Medical Ethics*. Chicago, IL: American Medical Association; 2006. http://www.ama-assn.org/ama/pub/category/8542.html. Accessed September 4, 2007.
[3] United States Patent Act, 35 U.S.C.S. § 101 (Matthew Bender 2006).
[4] United States Patent Act, 35 U.S.C.S. § 287(c) (Matthew Bender 2006).
[5] American Medical Association. Opinion 9.08 New Medical Procedures. *AMA Code of Medical Ethics*. Chicago, IL: American Medical Association; 2006. http://www.ama-assn.org/ama/pub/category/8540.html. Accessed September 4, 2007.

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